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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,053	10/12/2001	Carl Johan Friddle	LEX-0256-USA	1810

24231 7590 11/04/2003

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EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/977,053	Applicant(s) FRIDDLE ET AL.	
	Examiner Sharon L. Turner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 4-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2 and 4-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1-29-02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 9-3-03 has been entered into the record and has been fully considered. Claim 3 is canceled. Claims 1-2, 4-12 are pending.

Election/Restriction

2. Applicant's election with traverse of Group I, claims 1-2 to the extent of SEQ ID NO:4 in the Paper of 9-3-03 is acknowledged. The traversal is on the ground(s) that Group I and III are related. Subsequent search by the Examiner has revealed that SEQ ID NO:6 is linking to invention I in that SEQ ID NO:6 is completely encompassed by SEQ ID NO:4. Groups I and III are thus rejoined as to the linking structure of SEQ ID NO:6. Restriction of Group II is maintained in that the structures are uncommon to SEQ ID NO:4 and 6. Newly submitted claims 5-12 are drawn to the invention of rejoined Groups I and III and are under examination.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-2 and 4-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility.

The specification discloses that the claimed invention is related to isolated novel human proteins NHP's and contemplates the use of the disclosed nucleic acids for example in the, "generation of antibodies, as reagents in diagnostic assays, for the

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identification of other cellular gene products related to the NHP's, as reagents in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological or medical disorders and diseases such as but not limited to cardiovascular disease, hyperproliferative disorders, stenosis (or preventing restenosis) and connective tissue disorders," see in particular pp. 21, lines 18-28. Similarly related uses are disclosed throughout pp. 1-33 including for preparation of probes and primers for use in hybridizations, for production of proteins and mRNAs encoded by said genes and related nucleic acids. Also contemplated are uses for the various reagents related to the NHP molecules including nucleic acids, peptides and antibodies.

However, such utilities as disclosed do not appear to be either specific or substantial because these uses merely rely on the inherent properties of any nucleic acid to hybridize (bind) and encode. There is no specific information provided as to the use and/or function that is specific to the sequences of SEQ ID NO:4 and 6. The peptide is not exemplified as providing any particularly useful information, activity or function and the nucleic acids are not disclosed as indicative, prognostic or diagnostic to any particular condition such that the sequence reveals useful information to the artisan as to it's presence, absence or particular significance. The peptide is merely identified as a member of one of the broad genus of newly isolated human peptides and encoding nucleic acids for which no particularly useful information is provided as to how the artisan may specifically utilize the sequence to obtain immediate benefit and/or significance.

Accordingly, the disclosed nucleic acids merely constitute research reagents for further experimentation to discover the "real-world" significance or use of the nucleic acids claimed. The recited uses also do not constitute a well-established utility because the utility of the sequence is not established within the art. For these reasons there does not appear to be either a specific and substantial asserted utility or well-established utility for the claimed nucleic acids.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2 and 4-12 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 2 recites "highly" stringent conditions. Support for the recitation is found at p. 4, lines 28-31. However, the artisan cannot discern the metes and bounds of the recitation "highly" in that the claim is not limited to the particular conditions of the specification, and the art recognizes significant variability amongst the conditions recognized as being of "high" stringency as well as a variability amongst nucleic acid sequences that hybridize under any particular conditions, see in particular Sambrook et al., Molecular Cloning, Cold Spring Harbor Lab. Press, 1989, pp. 9.47-9.51 and 11.48-49. Clarification of the conditions that are "highly" stringent is required.

Further it is noted with respect to claim 2 that the complement is not encoding to SEQ ID NO:4 and is thus outside the scope of the claim. If applicants wish to receive protection as to the complements, a separate claim or appropriate amendment should be presented.

Status of Claims

9. No claims are allowed.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with

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the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

A handwritten signature in cursive script, appearing to read "Sharon L. Turner".

Sharon L. Turner, Ph.D.
November 3, 2003